# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DANE K. FISHER, and RAGHUNATH V. LALGUDI



Appeal No. 2005-1340
Application No. 09/394,745

HEARD: August 23, 2005

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 8-11, which are all the claims pending in the application.

Claim 11 is illustrative of the subject matter on appeal and is reproduced below:

11. A microarray comprising nucleic acid molecules that are comprised of different sequences and at least about 250 nucleotide residues, wherein said nucleic acid molecules comprise nucleic acid sequences complementary to SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896,

SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO: 5937, SEQ ID NO: 5939, SEQ ID NO: 5941, SEQ ID NO: 5944, SEQ ID NO: 5945, SEQ ID NO: 5950, SEQ ID NO: 5955, SEQ ID NO: 5960, SEQ ID NO: 5961, SEQ ID NO: 5963, SEQ ID NO: 5964, SEQ ID NO: 5968, SEQ ID NO: 5973, SEQ ID NO: 5974, SEQ ID NO: 5991, SEQ ID NO: 5994, SEQ ID NO: 5999, SEQ ID NO: 6000, SEQ ID NO: 6001, SEQ ID NO: 6005, SEQ ID NO: 6006, SEQ ID NO: 6007, SEQ ID NO: 6011, SEQ ID NO: 6017, SEQ ID NO: 6018, SEQ ID NO: 6022, SEQ ID NO: 6023, SEQ ID NO: 6026, SEQ ID NO: 6030, SEQ ID NO: 6033, SEQ ID NO: 6042, SEQ ID NO: 6046, SEQ ID NO: 6059, SEQ ID NO: 6063, SEQ ID NO: 6065, SEQ ID NO: 6066, SEQ ID NO: 6089, SEQ ID NO: 6091, SEQ ID NO: 6098, SEQ ID NO: 6106, SEQ ID NO: 6107, SEQ ID NO: 6110, SEQ ID NO: 6117, SEQ ID NO: 6121, SEQ ID NO: 6124, SEQ ID NO: 6131, SEQ ID NO: 6137, SEQ ID NO: 6141, SEQ ID NO: 6144, SEQ ID NO: 6145, SEQ ID NO: 6147, SEQ ID NO: 6154, SEQ ID NO: 6167, SEQ ID NO: 6168, SEQ ID NO: 6170, SEQ ID NO: 6173, SEQ ID NO: 6178, and SEQ ID NO: 6181.

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

## GROUNDS OF REJECTION

Claims 8-11 stand rejected under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.

Claims 8-11 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to provide an adequate written description of the claimed invention.

We affirm the utility rejections under 35 U.S.C. § 101 and § 112, first paragraph. Having disposed of all claims on appeal, we do not reach the merits of the written description rejection.

## PROCEDURAL BACKGROUND

The application was originally filed with seven claims. On October 10, 2000, appellants cancelled all pending claims and submitted claims 8-11. Claim 8, entered into the record on October 10, 2000, is similar to amended claim 8 now before us on appeal; one notable difference, however, is that the Markush grouping of nucleic acid molecules set forth in original claim 8 recited 497 nucleotide sequences by SEQ ID NO. On December 19, 2000, the examiner entered a Restriction Requirement into the record, which required appellants to select a patentably distinct group of invention from the group consisting of (I) claims 8-10; and (II) claim 11 for examination on the merits. In addition, as we understand the Restriction Requirement, if appellants elected Group I, they were further required to identify a defined group of nucleic acid molecules from the Markush grouping set forth in claim 8, for examination on the merits. In response, appellants elected, with traverse, the invention of Group I, claims 8-10, and the first 100 nucleic acid molecules set forth in original claim 8.[1] See

[1] At page 3 of the Office Action mailed September 11, 2002, the examiner explains "the actual combination of 'one hundred' SEQ ID Numbers was selected by Applicants, and was not required by the [e]xaminer. Applicants were requested to elect a single combination of nucleic acids (see Office Action mailed on December 19, 2000, on page 3) to which [a]pplicants have elected the 'first one hundred' SEQ ID Numbers as the elected combination ([a]pplicants' response on page 3, Paper No. 6, April 17, 1001). In other words, [a]pplicants could have elected all of the recited SEQ ID Numbers as the combination to be examined. However, it was [a]pplicants who have decided to elect the first 100 SEQ ID Numbers as the elected combination."

Response, entered April 17, 2001. On December 6, 2001, appellants clarified the record by specifically reciting the exact nucleic acid molecules elected.

On March 18, 2002, the examiner withdrew the Restriction Requirement as it relates to Groups I and II, accordingly claims 8-11 where examined on their merits. We note, however, the examiner expressly stated (Paper No. 11, mailed March 18, 2002), "the examination of SEQ ID Numbers will not go beyond the 100 SEQ ID Numbers" elected by appellants for examination on the merits. On June 18, 2002, appellants amended claim 8; among other things, this amendment limited the originally filed Markush grouping of nucleic acid molecules to the 100 sequences elected by appellants.[2]

Upon review of the record, the Restriction Requirement was in dispute throughout prosecution before the examiner, and into the appeal stage. See e.g., Supplemental Brief, received June 30, 2003, page 2. As we understand appellants' arguments, despite the fact that they amended claim 8 to include only the elected nucleic acid molecules, they argue that the original requirement to elect a set of nucleic acids was improper. Nevertheless, on page 2 of the Supplemental Answer, mailed November 12, 2004, the examiner withdrew the Restriction Requirement relating to the selection of a particular set of nucleic acid molecules. This procedural action on the part of the examiner, however, had no effect on the scope of amended claim 8 as it now appears on this record.

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[2] In addition, we note that appellants' amendment to claim 8 replaced the term "having" as it appeared after the term "[a] microarray" in line one of the claim with the term "comprising". This amendment is consistent with the examiner's construction of the term "having" as it appeared in the originally filed claim 8. See, page 3, Office Action mailed March 18, 2002, "[c]laims 8-10 recite the phrase, 'molecule having a sequence.' For the purpose of prosecution, the phrase is assumed to be open-ended and thus reading on the phrase, 'molecule comprising a sequence.'"

Further, we note there is no evidence of record that subsequent to the examiner's withdrawal of the species election appellants attempted to introduce a new claim, or amend claim 8, to reintroduce the remaining 397 non-elected nucleic acid molecules back into the claim.

In the end, as it appears before us on appeal, there is no restriction requirement of record in the application; and there is no pending claim on appeal that includes a Markush grouping of 497 SEQ ID NOs. as was set forth in claim 8 as originally filed. Accordingly, while we have considered appellants' arguments as presented in the Supplemental Brief relating to the failure of the examiner to examine a claim directed to a microarray comprising, inter alia, a Markush grouping of 497 SEQ ID NOs., there is no pending claim on appeal that includes such a grouping. We also note that the 497 nucleic acid molecules set forth in originally presented claim 11 was not subject to a Restriction Requirement. See, e.g., Restriction Requirement (mailed December 19, 2000, page 3), "[i]f group 1 (claims 8-10) is selected, examination will be restricted to only the elected combination." The Restriction Requirement makes no mention of the application of this "species" election to any of the 497 SEQ ID NOs. listed in original claim 11. Nevertheless, appellants subsequently amended (see appellants' amendment received June 18, 2002) claim 11 to limit the group of SEQ ID NOs. to the 100 SEQ ID NOs. presented in claim 11 on appeal.

## CLAIM GROUPING

According to appellants (Brief, received March 13, 2003, page 2), "[t]he patentability of claims 8-11 is addressed together...." Accordingly, we limit our discussion to representative independent claim 11. Claims 8-10 will stand or fall together with claim 11.

## CLAIM CONSTRUCTION

Claim 11 is drawn to a microarray comprising nucleic acid molecules (ESTs) that are comprised of different sequences. As we understand claim 11, these nucleic acid molecules (1) are at least about 250 nucleotide residues in length[3], and (2) comprise nucleic acid sequences complementary[4] to nucleic acid molecules represented by the Markush grouping of 100 SEQ ID NOs. recited in claim 11. See e.g., Supplemental Answer, page 4: claim 11 is "drawn to a microarray comprising nucleic acid molecules, the nucleic acid molecules of which are at least 250 residues in length and complementary to nucleic acid molecules represented by their SEQ ID Numbers."

As to the SEQ ID NOs. set forth in claim 11, we note that according to appellants' specification (page 92, lines 13-14), "SEQ ID NO: 5746 through SEQ

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[3] See e.g., appellants' specification, page 16, lines 20-25 "[a]gents of the present invention include nucleic acid molecules and more specifically EST nucleic acid molecules or nucleic acid fragment molecules thereof. Fragment EST nucleic acid molecules may encode significant portion(s) of, or indeed most of, the EST nucleic acid molecule. Alternatively, the fragments may comprise smaller oligonucleotides (having from about 15 to about 250 nucleotide residues, and more preferably, about 15 to about 30 nucleotide residues)."

[4] According to appellants' specification (page 18, lines 11-13), "the molecules are said to be 'complementary' if they can hybridize to one another with sufficient stability to permit them to remain annealed to one another under conventional 'high-stringency' conditions."

ID NO: 8666 are from [the] LIB189" cDNA library. As appellants' specification explains (page 92, lines 8-13), the LIB189 cDNA library was prepared from leaf tissue harvested at anthesis from field grown Zea mays genotype RX601 plants that "were open pollinated plants in a field (multiple row) setting."

## DISCUSSION

Utility:

The examiner rejected all of the claims as lacking patentable utility.[5] Initially, we note that the claimed microarrays contain nucleic acid molecules (ESTs) isolated from the LIB189 cDNA library, which was prepared from leaf tissue harvested at anthesis from field grown Zea mays genotype RX601 plants.[6] There is no evidence on this record that LIB189 is a subtractive cDNA library, wherein nucleic acid molecules from maize tissue other than leaf tissue, from developmental stages other than anthesis, and/or from Zea mays plants other than genotype RX601 is subtracted (removed) from the library. Thus, as we understand claim 11, the nucleic acid molecules associated with the claimed microarray represent 100 randomly selected nucleic acid molecules isolated from

[5] The examiner rejected the claims under both 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. However the rejection for nonenablement was presented simply as a corollary of the finding of lack of utility. See Supplemental Answer, page 5. Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

[6] Accordingly, we disagree with appellants' assertion (first Brief, page 10), "[t]he nucleic acid molecules of the claimed microarray are isolated, for example, from various samples derived from Zea mays such as ear tissue, kernel tissue, mature pollen, etc...." There is no doubt that appellants' specification (pages 91-99), discloses nucleic acid molecules isolated from cDNA libraries produced from different parts of Zea mays plants. There is, however, no requirement in the claims before us on appeal, or in claims 8-11 as originally presented, that nucleic acid from these other cDNA libraries be included on the claimed microarray. Note, that the SEQ ID NOs. set forth in claims 8-11 as originally presented are from the same cDNA library, LIB189.

pooled leaf tissue isolated from Zea mays genotype RX601 at the time of anthesis. There is, however, no evidence on this record that any of these 100 randomly selected nucleic acid molecules are expressed only at the time of "anthesis," only in leaf tissue, or only in a Zea mays plant having the RX601 genotype.

While, appellants provide SEQ ID NOs for these 100 nucleic acid molecules, appellants fail to identify any other characteristic of these nucleic acid molecules. As the examiner points out (Supplemental Answer, page 4), "[t]he specification identifies these SEQ ID Numbers as varying in length, but no open reading frame, start/stop codons, or encoded protein is identified in the specification and sequence listing of the SEQ ID Numbers." Simply put, appellants' disclosure tells a person of ordinary skill in the art nothing about any of the 100 nucleic acid molecules other than their sequence.

Accordingly, the question before us is whether appellants have satisfied the utility requirement for a claim drawn to a microarray comprising 100 nucleic acid molecules that are, but for their sequence, uncharacterized. For the following reasons, it is our opinion that appellants have not.

According to the examiner (Supplemental Answer, page 4), appellants have identified a number of utilities for the claimed microarray including screening for biological molecules, expression profiling and identifying polymorphisms. The examiner finds, however,

> [n]one of these are considered to be specific and substantial in view of the limited information provided in the specification. No traits are attributed to the combination of the recited SEQ ID Numbers. No complete gene is disclosed nor DNA

> maps/chromosomal location identified. No polymorphisms are identified within the claimed nucleic acids. The specification simply fails to disclose that any of the SEQ ID Numbers contain any polymorphism. Even if arguendo, such polymorphisms were disclosed, a disclosure of what immediately applicable information the presence of the absence of such polymorphisms would provide to a skilled practitioner would be required to which the specification does not provide.

Id. In addition the examiner finds (Supplemental Answer, page 5),

> [f]urther research and experimentation would be required to identify a full length sequence that comprise[s] the claimed SEQ ID Numbers. Further research and experimentation would also be required to determine any associated traits and/or function(s) encoded. Identifying and studying the properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define a "real world" context of use.

Appellants make the following arguments:

I. Pirrung[7] and Fodor[8]:

As we understand appellants' arguments (Brief, page 5), Pirrung and Fodor demonstrate that those of ordinary skill in the art would understand that the microarray of claim 11 is useful in processes that included "screening for biological activity, determining relative binding affinity for a molecule bound to the claimed microarray and creating a gradient of claimed nucleotide sequences in differing concentrations." Fodor's invention is directed at an array of oligonucleotides on a solid substrate. See e.g., Title and claims 1 and 7. There is no doubt that Fodor discloses (column 10, lines 28-30) that such an array can be used to screen for biological activity. We note, however, that in contrast to appellants' claimed invention, the array set forth in Fodor's claims is not limited

[7] Pirrung et al. (Pirrung) 5,143,854 Sep. 1, 1992

to any particular nucleic acid molecules. The same is true of the invention set forth in Pirrung's claims. Thus, in each of Fodor and Pirrung, the skilled artisan is free to select the relevant reagent (e.g., nucleic acid) of their choice to attach to the array. In contrast, appellants' claimed invention is directed to a microarray that comprises specific nucleic acid molecules identified by SEQ ID NO. Accord, Supplemental Answer, page 9. Therefore, the question is not whether microarrays are generally useful; to the contrary, the question is whether appellants have satisfied the utility requirement for a very specific microarray that comprises 100 nucleic acid molecules (ESTs) identified by SEQ ID NO., as set forth in appellants' claim 11.

Accordingly, to the extent that appellants assert that microarrays in general may have utility as demonstrated by Pirrung and Fodor, we agree. To the extent that appellants assert that Pirrung and Fodor demonstrate that the specific microarray set forth in appellants' claim 11 is useful, we disagree. In our opinion, the utility of a microarray is dependent on the reagent, in this case the nucleic acid molecules, associated with the microarray. In this regard, appellants assert (First Brief, page 10), the microarray of claim 11 "allow[s] one of ordinary skill in the art to design or customize a particular microarray tailored to the specific requirements of the artisan himself." While this may be true of the microarrays taught by Pirrung and Fodor, it is not true for the microarray set forth in appellants' claim 11. The microarray of appellants' claim 11 requires that the nucleic acid molecules comprise nucleic acid sequences complementary to the recited SEQ ID NOs. Thus, contrary to appellants' assertion, a person of

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[8] Fodor et al. (Fodor) 5,445,934 Aug. 29, 1995

ordinary skill in the art wishing to use the microarray of appellants' claim 11 is confined to the use of nucleic acid molecules that comprise nucleic acid sequences complementary to the recited SEQ ID NOs. Thus, the utility of the microarray set forth in appellants' claim 11 is dependent on the nucleic acid molecules associated with the microarray, specifically those that comprise nucleic acid sequences complementary to the recited SEQ ID NOs. However, as discussed above, the only information appellants have disclosed about these nucleic acids is their SEQ ID NOs. We also disagree with appellants' assertion (Brief, page 7), "[t]he claimed microarrays of the present invention are comprised of nucleic acid molecules isolated from various tissue of Zea mays (e.g., ear tissue, pollen, kernel tissue, anther tissue, etc.)...." As discussed above, the microarray of claim 11 comprises nucleic acid molecules isolated from leaf tissue.

Therefore, we look to the remainder of appellants' arguments with an eye toward the significance of the 100 nucleic acid molecules that are required components of the microarray set forth in appellants' claim 11. Specifically, the microarray set forth in appellants' claim 11, wherein the only information appellants have disclosed regarding the nucleic acid molecules on the microarray is their sequences.

II. Asserted Utilities:

According to appellants (Brief, pages 5-6, footnotes omitted), the claimed microarrays are useful (a) in screening for biological molecules, (b) as

hybridization probes for expression profiling, (c) in screening for biological activity, (d) determining relative binding affinity for a molecule bound to the claimed microarray, (e) creating a gradient of claimed nucleotide sequences in differing concentrations, and (f) to measure the level of mRNA in a sample. In response the examiner asserts (second Answer, page 11),

> [a]ppellants merely isolated the nucleic acids and immobilized them on the microarrays' substrate. Appellants have not tested, evaluated, or calibrated the claimed microarrays for any particular use. Therefore, an expression profiling assay using the claimed microarray would not have any meaning absent some correlation to an immediate benefit. An artisan would not know why a particular microarray comprising the claimed set of nucleic acid molecules should be used in a hybridization assay over another microarray comprising an entirely different set of nucleic acid molecules derived from maize plants. Therefore, an artisan would not know, previous to further experimentation, how to use the claimed microarray for a substantial use (i.e., what meaning could be derived from using the claimed microarray).

We agree.

> According to page 34 of appellants' specification:
>
> The nucleic acid molecules and fragments thereof of the present invention are generated from the cDNA library, LIB189, prepared from Zea mays pooled leaf tissue harvested from field grown plants. Leaves are the carbohydrate factories of crop plants, therefore, the ESTs of the present invention will find great use in the isolation of a variety of agronomically significant genes, including but not limited to genes that are necessary to for [sic] the interception and transformation of light energy via photosynthesis linked with plant growth, quality and yield. Genes isolated using the disclosed ESTs would also be in pathways including but not limited to a pathway such as nitrogen metabolism linked to fruiting and mobilization and distribution of nitrogen.

As we understand appellants' specification, the claimed microarray comprising 100 nucleic acid molecules isolated from the LIB189 cDNA library is useful in the isolation of a variety of agronomically significant genes. There is, however, no

evidence on this record that any "agronomically significant genes" could be isolated using the claimed microarray. As discussed above, other than their sequence, as represented by their SEQ ID NO., appellants have provided no other characterization of the nucleic acid molecules associated with the microarray of claim 11.

At page 42 of their specification appellants disclose,

> [t]he nucleic acid molecules of the present invention may be used to isolate promoters of tissue enhanced[,] tissue specific, cell-specific, cell -type, developmentally or environmentally regulated expression profiles. Isolation and functional analysis of the 5' flanking promoter sequences of these genes from genomic libraries, for example, using genomic screening methods and PCR techniques would result in the isolation of useful promoters and transcriptional regulatory elements.

There is, however, no evidence on this record that the claimed microarray is useful in isolating a promoter or other transcriptional regulatory elements.

Appellants argue (Brief, page 11), "[t]here can be no question that one skilled in the art can use the claimed microarrays ... to detect a mutation affecting the concentration of an mRNA or the pattern of expression encoded by one or more of the nucleic acid molecules present on a claimed microarray." According to appellants (Brief, page 12), this use of the claimed microarrays "enables a plant breeder to determine the potential of the expression response affecting a particular trait based on the genetic material in the progeny of a cross." Initially, we note that, contrary to appellants' assertion, there is no evidence on this record that any of the SEQ ID NOs. would be capable of detecting a mutation that affects the concentration of an mRNA or the pattern of expression encoded by one or more of the nucleic acid molecules present on the

microarray set forth in claim 11. Further, even if one or more of the nucleic acid molecules associated with the microarray of claim 11 was capable of detecting such a mutation, appellants have failed to identify a trait associated with any of the nucleic acid molecules associated with the microarray of claim 11. Thus, contrary to appellants' assertion there is no evidence on this record that a plant breeder would be able, without further experimentation, to use the microarray of claim 11 to determine the potential of the expression response affecting a particular trait based on the genetic material in the progeny of a cross.

Appellants also assert (Brief, page 8), "[o]ther uses for the claimed microarrays are as probes for a multitude of biological molecules, such as nucleic acid homologues or transcription factors, or as a means to assay relative binding efficiency of such molecules." There is no evidence on this record that any of the nucleic acid molecules associated with the microarray of claim 11 would be capable of recognizing other "biological molecules." Further, even if they did since the nucleic acid molecules associated with the microarray of claim 11 are uncharacterized but for their sequence, it is unclear from appellants' specification what information would be derived from the binding of such a biological molecule to appellants' uncharacterized nucleic acid molecule. For example, appellants assert (Brief, page 9, footnote omitted), "the claimed microarrays can be used in real world applications ... to isolate nucleic acid molecules of plants and organisms such as alfalfa, Arabidopsis, barley, Brassica, cotton, sunflower, Phaseolus, etc." Stated differently, the uncharacterized nucleic acids associated with the microarray of claim 11 could be used to identify

nucleic acid homologues from other plants and organisms. We question the utility of using an uncharacterized nucleic acid molecule to find other nucleic acid molecules in other plants and organisms that would also be uncharacterized.

According to appellants (First Brief, page 10, footnote 6), the nucleic acid sequences associated with the microarray of claim 11 have a "common utility as gene-specific hybridization targets to quantitatively measure expression of corresponding plant genes in Zea mays." We note, however, that since the only information disclosed by appellants regarding these nucleic acid molecules is their sequence, further research would be required to determine the significance of any data obtained by quantitatively measuring the expression of a plant gene that corresponds to any nucleic acid molecule associated with the microarray of claim 11.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370, 76 USPQ2d at 1229. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at 1371, 76 USPQ2d at 1229. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that

that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an asserted use must show that that claimed invention can be used to provide a well-defined and particular benefit to the public." Id.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. at 1373, 76 USPQ2d at 1231. "Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice but to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at 1374, 76 USPQ2d at 1232.

"Furthermore, Fisher's seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101." Id.

On this record, claim 11 is drawn to a microarray comprising 100 nucleic acids that appear to be randomly selected from the 2,920 nucleic acid molecules identified by appellants to be present in LIB189.[9] But for their sequence appellants have disclosed no other information regarding these nucleic acid molecules. As to the utility of the nucleic acid molecules themselves, we find Fisher to be controlling. This case differs from Fisher in that appellants have placed these uncharacterized nucleic acid molecules (ESTs) on a microarray. However, for the foregoing reasons, we find that on this record appellants have not satisfied the utility requirement for a claim drawn to a microarray comprising 100 nucleic acid molecules that are, but for their sequence, uncharacterized.

Accordingly, we affirm the rejection of claim 11 under 35 U.S.C. § 101, and the enablement provision of 35 U.S.C. § 112, first paragraph. As set forth above claims 8-10 fall together with claim 11.

Written Description:

Having disposed of all claims on appeal, we do not reach the merits of the rejection under the written description provision of 35 U.S.C. § 112, first paragraph.

[9] According to appellants' specification (page 92), "SEQ ID NO: 5746 through SEQ ID NO: 8666 are from LIB189."

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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